

REMARKS

Amendment to the Claims

Claims 12 and 14-20 were pending. Applicant has amended claims 15-18 and canceled claims 12 and 14. Accordingly, claims 15-20 will be pending after entrance of this amendment.

Withdrawal of Newly Added Hydrate Species

The Examiner indicates that Applicant's amendment to add a hydrate species in claims 12, 14-15, and 17-20 is withdrawn from consideration as being drawn to a non-elected species. In order to expedite prosecution, all references to a hydrate species have been deleted from the pending claims.

Rejection for Lack of Novelty

Claims 12 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Funahasi et al. (WO 02/032872). The Examiner's rejection appears to be based on the assumption that Funahasi et al. teaches that the elected compound (a) inhibits tumor cell proliferation and (b) can be used as a "pulmonary treatment agent." Based on these teachings the Examiner appears to be taking the position that the use the elected compound to treat small cell lung cancer is anticipated.

Applicant respectfully disagrees with this rejection. However, solely in order to expedite allowance of this case, Applicant has canceled claims 12 and 14. These amendments are made without prejudice and without intent to acquiesce in any rejection of record. Applicant reserves the right to pursue these claims in a continuation application.

Rejection for Obviousness

Claims 12, 14-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Funahasi et al. (WO 02/032872) in view of Hibi et al. (*Oncogene* 6:2291-2296, 1991). As noted above, claims 12 and 14 have been canceled therefore claims 15-20 remain. Applicant respectfully disagrees with this rejection as applied to claims 15-20. In particular, the Examiner has failed to explain how Funahasi et al. alone (or in combination with Hibi et al.) teaches each and every limitation of these claims. The Examiner has therefore failed to establish that these

claims are anticipated or *prima facie* obvious in view of the cited references. In particular, the Examiner's obviousness rejection only appears to address the treatment of small cell lung cancer as claimed in canceled claims 12 and 14. The Examiner has yet to point to any teaching in Funahasi et al. (alone or combined with Hibi et al.) of:

- (a) a method which includes an active step of confirming that cancer cells from a patient are expressing excessive c-Kit kinase or a mutant c-Kit kinase (see claims 15 and 19);
- (b) a method which involves treating mastocytosis, allergy or asthma (see claims 16 and 18); or
- (c) a method which involves applying a claimed compound to a cell expressing excessive c-Kit kinase or a mutant c-Kit kinase (see claims 17 and 20).

In addition, the Examiner cannot presume that because c-Kit is expressed in small cell lung cancer and because the elected compound is taught as a "pulmonary treatment agent" in Funahasi et al. then it must be acting as a c-Kit kinase inhibitor in Funahasi et al. Indeed, therapeutic agents for lung cancers do not necessarily show c-Kit kinase inhibitory activity. For example, Iressa[®] (Gefitinib or ZD1839) which can be used to treat non-small cell lung cancer is an EGFR-TK (epidermal growth factor receptor-tyrosine kinase) inhibitor (e.g., see Wakeling et al., *Cancer Research*, 62: 5749-5754 (2002), Naruse et al., *Int. J. Cancer*, 98: 310-315 (2002) and Ciardiello et al., *Int. J. Cancer*, 98: 463-469 (2002) which are provided in the Supplemental Information Disclosure Statement filed herewith). The same is true of Tarceva[®] (Erlotinib). If the presently claimed invention is obvious in view of the cited references, then it would logically follow that Iressa[®] and Tarceva[®] must also have c-Kit kinase inhibitory activity. However, it is uncertain whether Iressa[®] and Tarceva[®] have c-Kit kinase inhibitory activity. In other words, a person of ordinary skill cannot predict which therapeutic agents show c-Kit kinase inhibitory activity among therapeutic agents for lung cancer. Therefore, it would not have been obvious to a person of ordinary skill that because c-Kit is expressed in small cell lung cancer and because the elected compound is taught as a "pulmonary treatment agent" in Funahasi et al. then it must be acting as a c-Kit kinase inhibitor in Funahasi et al. For all of these reasons, the Examiner's obviousness argument is flawed and should be withdrawn.

In view of these deficiencies, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 15-20.

Conclusion

Applicant respectfully submits that the amended claims are in condition for allowance. If it is believed that a telephone conversation would help further expedite allowance of this case, or if any further information is required, the Examiner is invited to contact the undersigned at (617) 248-4793. Additionally, please charge any fees that may be required, or credit any overpayment, to our Deposit Account No. 03-1721.

Respectfully submitted,

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